



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,253	04/04/2005	Maria C. Cassetti	00630/100M137-US2	5501
32801	7590	06/21/2006	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 5257 NEW YORK, NY 10150-5257			SALIMI, ALI REZA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/530,253	CASSETTI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 5-10,13-15,17-20 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,11,12,16 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/12/06; 4/4/05</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1648

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I (Claims 1-4, 11, 12, 16, and 21) in the reply filed on 05/12/2006 is acknowledged. The traversal is on the ground(s) that nothing in Edwards patent teaches or suggests the importance of the mutation of the residues set forth in claim 1. This is not found persuasive because the fusion protein taught by Edwards contains the majority of shared structural elements that's claimed. The functional and structural similarity that is taught in prior art and now claimed molecules cannot be considered to form the contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-10, 13-15, 17-20, 22-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/12/2006.

**Applicant is reminded to cancel the claims to the non elected Group(s).**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1648

Claims 1-4, 11, 12, 16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dalal et al (Journal of Virology, 1996, Vol. 70, No.2, pages 683-688), and Bruck et al (WO 99/10375).

Dalal et al disclosed series of human papillomavirus type 16 (HPV-16) early protein 6 (E6) mutants and taught mutant at location 106, and 63 which neither affected binding nor degradation of p53 (see the abstract, Table, 1, and Figure 2). This differs since they did not teach fusion of E6 to E7 protein.

Bruck et al taught fusion of papillomavirus early proteins E6 and E7 having various mutations including at amino acids 24, and 26 (see page 38, and the claims). Additionally, the cited reference taught adjuvant and immunogenic composition (see page 42, and the claims).

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated by the above teachings to include the mutations taught by Dalal et al and fuse the E6 protein to E7 having selective mutation as taught by Bruck et al for the composition to induce immune response in a suitable host. One of ordinary skill in the art being familiar with the above cited art would not have anticipated any unexpected results. Certain limitations are seen as a design choice unless the proof of criticality is proven. Thus, the invention as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

Art Unit: 1648

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

06/16/2006

ALI R. SALIMI  
PRIMARY EXAMINER